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PATENT APPLICATION
Docket No. 1420-002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of:	David William House		
Confirmation No.	1290		
Serial No.	09/478,136	Group No.	2615
Filed:	January 5, 2000	Examiner:	Suhan Ni
Title:	COCHLEAR IMPLANTS WITH A STIMULUS IN THE HUMAN ULTRASONIC RANGE AND METHOD FOR STIMULATING A COCHLEA		
Date:	August 17, 2006		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Responsive to the Office Action, Paper No. 60504, dated May 17, 2006, please amend the application as follows.

Claims begin on page 2.

Remarks begin on page 4.

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CLAIMS

Amend the claims as follows.

1. – 6. (Canceled)

7. (Previously presented) A cochlear implant system for a patient's cochlea comprising:

at least one electrode for electrical coupling with the patient's cochlea;

an internal coil for implanting in the patient to drive the at least one electrode;

a microphone for outputting electrical sound signals in response to external sounds;

an oscillator for generating an electrical analog carrier signal having a frequency greater than 20 kHz;

a modulator for modulating the carrier signal with the sound signals to generate a modulated signal; and

an external coil for magnetically coupling the modulated signal to the internal coil such that the modulated signal is electrically directly applied to the cochlea to cause a percept.

8. (Original) The system of claim 7, wherein the modulator is an amplitude modulator.

9. (Original) The system of claim 7, wherein the modulator is a frequency modulator.

10. (Original) The system of claim 7, wherein the electrical analog carrier signal has a frequency of at least 32 kHz.

11. (Original) The system of claim 10, wherein the modulator is an amplitude modulator.

12. (Original) The system of claim 10, wherein the modulator is a frequency modulator.

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13. (Previously presented) The system of claim 7 comprising at least one reference electrode for providing a reference voltage to the at least one electrode.

14. (Previously presented) The system of claim 14 wherein the modulated signal allows a wearer of the implant system to hear frequencies higher than air-conducted sonic human hearing sensitivity.

15. (New) The system of claim 13 where the internal coil includes a first terminal for connecting to the at least one electrode and a second terminal for connecting to the at least one reference electrode.

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REMARKS

The application includes claims 7-14 prior to entering this amendment.

The examiner rejects claims 7-14 under 35 U.S.C. § 103(a) as being unpatentable over Applicant Admitted Prior Art (AAPA) in view of Lippa et al (U.S. Patent No. 6,377,693).

The applicant amends no claims and adds claim 15.

The application remains with claims 7-15 after entering this amendment.

The applicants add no new matter and request reconsideration.

Claim Rejections Under § 103

The examiner rejects claims 7-14 as old over AAPA in view of Lippa. The applicants disagree for the reasons that follow.

Lippa discloses a method and apparatus for treating tinnitus that involves generating a noise masking signal to mask the ringing or buzzing in the ears caused by tinnitus, and transposing that masking signal into the ultrasonic range. The noise masking signal, when applied vibrationally or sonically, "effectively masks the tinnitus noise without interfering with the subject's perception of normal sounds such as human speech." Abstract.

Put differently, Lippa's noise masking signal is specifically generated, modulated, amplified, and applied such that it is not perceived by the user so as to not interfere with the user's hearing. Column 2, lines 8-10.

Moreover, although Lippa discloses applying the ultrasonically modulated signal "to the body," it does not apply the ultrasonic modulated signal directly to the cochlea as required by the claims. In referring to its embodiment in Figure 1, Lippa discloses that applicator 16 "may be an electric/vibratory transducer such as a piezoelectric driver attached to the skull for bone conduction, or it may in the form of a speaker which creates physical vibrations in the air, which vibrations are transmitted in wave form through the air." Lippa, column 2, lines 25-32. Although Lippa goes on to disclose that the "applicator 16 may be an electrode which directly applies an electromagnetic signal to a selected portion of the body," it does so clearly to mask the "ringing or buzzing in the ears associated with tinnitus, while not interfering with the perception of speech or other normal sounds" (column 2, lines 34-36). That is, the applicator 16 does not apply the masking signal directly to the cochlea to create a percept of the masking signal itself because it would obviously interfere with speech or other normal sounds.

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Further, although Lippa's applicator 16 may apply a signal to a "selected portion of the body," the only identified body portions are the skull ("attached through the skull for bone conduction," column 2, line 27) and other bony structures ("applied vibrationally through bone conduction," column 2, lines 51). The cochlea is not the skull or a bony structure.

The examiner proposes that it would have been "obvious to one skilled in the art... to provide ultrasonic modulation for the [AAPA] system, in order to provide a hearing device with less interference, such as with tinnitus masking." For decades, however, the belief has been that stimulus frequencies above 3-4 kHz were irrelevant to stimulating sensory nerves because of what was then known about the workings of nerves. Decades of nerve research provided for the notion that nerves fire, and this activity happens at a very low frequency. That is, the nerve is supposed to have calcium (-) and sodium (+) ions on either side of a membrane, and when the nerve fires, these ions exchange places so that a wave travels along the nerve. It was well known that if you stimulate nerves with pulses that exceeded, say, 1500 pps, the nerve would go into refractory, and would thereafter refuse to fire. This is why virtually all patents for cochlear implants, which stimulate the cochlea using multiple electrodes and pulsatile stimulus, describe stimulation only as high as 1500 pps.

The reason for the firing view of nerves has likely to do with the very limited tools available for this kind of research. That is, *pulses* were the tool of choice, because they provide repeatable results when trying to discern what a sensory nerve is doing in situ. Sine and similar waves were not used as a stimulus in such research, in spite of the fact that the body produces no pulses naturally. Across many decades, a picture of nerve activity that emphasized that nerves were, apparently from all the available data, pulsatile creatures, grew up and took hold. Nerves, the data showed, indeed fired.

The reason for Lippa to use higher frequency signals, then, was certainly *not* with the idea that a high frequency stimulus would somehow be directly utilized by the nerve. Rather, higher frequency signals were used to overcome skin resistance, and because it was reliably thought that the body would demodulate the signal and provide the brain with the lower frequency (demodulated) stimulus therein.

The applicants know of no reference (and the examiner appears to have found none) that describe direct electrical stimulus of the cochlea at anything above 20 kHz. Others have described the indirect electrical stimulus of the head with high frequency signals and perhaps, vibrational stimulus of the head with high frequency energy. No reference exists, however,

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describing the direct stimulation of the cochlea using an electrical signal modulated at greater than 20 kHz to achieve a percept.

The examiner's conclusion, therefore, that it would have been obvious to combine the AAPA with Lippa's ultrasonic masking signal to provide a hearing device with less interference, is without merit when one considers that a person of reasonable skill in the art would understand nerves to fire at frequencies below 3 kHz and, consequently, not to fire (or create a percept) at higher frequencies. A person of reasonable skill in the art would also know that signals having frequencies higher than 3 kHz are used for external body application, and not directly applied to the (internal body) cochlea to create a percept as required by the claims.

On a final note, Lippa does not indicate that its method and apparatus will allow the deaf to hear. Lippa exclusively addresses the masking of the buzzing noise created by tinnitus using an ultrasonic masking signal. That a person of reasonable skill in the art would look to a method and apparatus intended to mask tinnitus buzzing in a hearing person to provide hearing to a deaf person is nonsensical, and as developed above, contrary to all known research of the time.

The examiner rejects claim 13 as being obvious over the AAPA in view of Lippa. The applicants note, however, that neither the AAPA nor Lippa make mention of a reference electrode, much less a reference electrode connected to a second terminal of the internal coil as recited in new claim 15.

Conclusion

The applicants request reconsideration and allowance of all remaining claims. The applicants encourage the examiner to telephone the undersigned at (503) 222-3613 if it appears that an interview would be helpful in advancing the case.

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Respectfully submitted,

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